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EXAMINER	
FLOOD, MICHELE C	
ART UNIT	**PAPER NUMBER**
1654	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/716,163	MAYO-ALVAREZ ET AL.	
	Examiner	Art Unit	
	Michele Flood	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Miller et al. (A) and Margetts et al. (F).

Applicant claims a pharmaceutical composition comprising: a. an analgesic selected from the group consisting of morphine, meperidine, fentanyl, hydromorphone, oxymorphone, oxycodone, hydrocodone, methadone, propoxphene, pentazocine, levophanol and combinations thereof; and, b. a stool softener. Applicant further claims the pharmaceutical composition of claim 1, wherein the stool softener is selected from the group consisting of docusate, poloxamer 188, psyllium, bisacodyl, castor oil, magnesium citrate, magnesium hydroxide, magnesium sulfate, dibasic sodium phosphate, monobasic sodium phosphate, sodium biphosphate and combinations thereof. Applicant further claims the pharmaceutical composition of claim 1, formulated as at least one member of the group consisting of an oral solution, oral syrup, soft gelatin capsule, hard gelatin capsule, tablet, capsule and sterile packaged powder.

Miller teaches a pharmaceutical composition comprising morphine (an analgesic), poloxamer 188 (a stool softener), and magnesium sulfate (a stool softener), which are formulated in the form of a tablet, in Table V.

In Column 15, lines 50-68, Margetts teaches a pharmaceutical composition comprising codeine and sodium dioctyl sulfosuccinate (docusate, a stool softener), which is formulated in the form of a tablet.

The references anticipate the claimed subject matter.

Claims 1, 2, 5 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by LaHann (B).

Applicant's claimed invention of Claims 1, 5 and 10 was set forth above. Applicant further claims the pharmaceutical composition of claim 1, further comprising a non-opioid analgesic.

LaHann teaches a pharmaceutical composition comprising codeine or propoxyphene (analgesics), N-vanillyl-1-E-octadecenamide (non-opioid analgesic), and methylcellulose (stool softener) in the form of an oral solution, in Column 8, lines 27-68.

The reference anticipates the claimed subject matter.

Claims 1, 5, 10, 21 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Brown et al. (N).

Applicant's claimed invention of Claims 1, 5 and 10 was set forth above. Applicant claims a method of preventing constipation during analgesic use

comprising administration of a pharmaceutical composition comprising a stool softener with an analgesic in a single oral dosage form, wherein said analgesic is selected from the group consisting of morphine, meperidine, fentanyl, hydromorphone, oxymorphone, oxycodone, hydrocodone, methadone, propoxphene, pentazocine, levophanol and combinations thereof.

Brown teaches a pharmaceutical composition comprising morphine (an analgesic) and bisacodyl (a stool softener) and a method of reducing the constipation in a patient receiving opioid analgesia comprising the oral administration of the aforementioned composition. *See* page 1 of the patent, lines 17-23. On page 4, lines 1-5, Brown teaches that the reference composition may take the form of tablets, capsules, granules, spheroids, powders, suspensions or liquid preparations. On page 4 of the patent, lines 17-20, Brown further teaches that the pharmaceutical composition may be present in control release form or normal release form. *See* page 8 of the patent, wherein Miller teaches a sustained release form tablet in single dose form comprising the instantly claimed ingredients. On page 2, lines 12-18, Brown also teaches that typical opioid analgesics, *e.g.*, hydromorphone, may be used in the making of the taught composition.

The reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 5, 8-12, 16-19, 21, 25, 28-30, 33 and 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lazarus et al. (U), as evidenced by the teachings of http://www.drugs.com/ODR/Senokot_Tablets.html (W1).

Applicant's claimed invention of Claims 1, 5, 21 and 30 was set forth above. Applicant further claims the pharmaceutical composition of claim 1, wherein the stool softener comprises from about 10 mg to about 300 mg of docusate; and, wherein the stool softener comprises from about 50 mg to about 100 mg of docusate. Applicant further claims the pharmaceutical composition of

claim 1, further comprising a sustained release carrier that causes the analgesic to be released over a period of about 4 to about 16 hours when orally administered to a human patient. Applicant claims a method of preventing constipation during analgesic use comprising administration of a single solid dosage form comprising a. an opioid analgesic; and, b. at least about 50 mg of docusate.

Lazarus teaches a method of alleviating opioid-induced constipation comprising orally administering controlled-release morphine sulfate and 60-180 mg of Senokot-S® (a combination laxative and stool softener containing senna and 50 mg of docusate, as evidenced by the teachings of drugs.com). *See* abstract.

The teachings of Lazarus are set forth above. Lazarus does not teach the oral administration of the two drugs in a single dosage form to provide a method for the prevention of opioid-induced constipation in a human patient. However, it would have been obvious to one of ordinary skill in the art to combine the two drugs taught by Lazarus to form a pharmaceutical composition comprising an opioid analgesic and a stool softener to provide the instantly claimed method and instantly claimed composition because Lazarus teaches that the simultaneous administration of morphine and docusate reduces the frequency of constipation in patients receiving pain control treatment by the administration of an opioid analgesic, on page 12, line 38 and page 13 in its entirety. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to modify the form

of the pharmaceutical composition and the method of oral administration of the two ingredients taught by Lazarus to provide the instantly claimed inventions because it would have been merely a matter of judicious selection to pick and choose the dosage form of the ingredients comprising the pharmaceutical composition given that the reference before him or her clearly teaches that the ingredients when simultaneously and orally administered provide the claim-designated functional effect for the prevention of constipation in humans receiving opioid analgesic treatment, especially since a single dose form would provide a convenient and easy dosage form for administration to patients in need of such therapeutic treatment; and, since Lazarus teaches, "Controlled-release oral morphine sulfate (MS Contin® Tablets*; MSC), represents an innovation over conventional immediate-release morphine and over the longer-acting narcotics because of its convenient 12-hour dosing schedule and ease of administration combined with an efficacy and safety profile at least equal to that seen with conventional oral morphine", on page 3, lines 13-21.

According, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 1-5, 8-25 and 28-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lazarus et al. (U) in view of Raeder et al. (V), Mullican et al. (W), Marketletter (X), Maurer et al. (U1) and Rauk et al. (V1).

Applicant's claimed inventions for Claims 1, 5, 8-12, 16-19, 21, 25, 28-30, 33 and 37-39 were set forth above. Applicant further claims the pharmaceutical compositions of claim 12 and 33, further comprising a non-opioid analgesic; wherein the non-opioid analgesic is acetaminophen; wherein the non-opioid analgesic acetaminophen is about 10 mg to about 2000 mg of acetaminophen; and, wherein the non-opioid analgesic acetaminophen is about 325 mg to about 750 mg of acetaminophen. Applicant further claims the pharmaceutical of claim 12 and the method of claim 33, wherein the opioid analgesic is codeine. Applicant further claims the method of claim 21, wherein the single oral dosage form is administered with food.

A method of preventing constipation during analgesic use comprising administration of a single solid dosage form comprising an opioid analgesic and at least about 50 mg of docusate is set forth immediately above, as obviated by the teachings of Lazarus. The obvious teaching of Lazarus teaches the instantly claimed inventions except for wherein the single dose and the method for the oral administration thereof prevents constipation comprises the non-opioid analgesic acetaminophen; and, wherein the opioid analgesic is codeine. However, it would have been obvious to one of ordinary skill in the art to add acetaminophen and to add and/or replace the morphine with codeine taught by the single oral dosage form and method of use thereof taught by the obvious teachings of Lazarus, as set forth immediately above, to provide the instantly claimed inventions because at the time the invention was made it was known in the art that the instantly claimed ingredients were useful in the making of pharmaceutical compositions for

analgesic purposes but that the oral administration of the combination of the two ingredients during oral administration to human subjects to provide an analgesic effect caused constipation, as evidenced by the teachings of Raeder, Mullican, Marketletter, Maurer and Rauk; and, it was also known in the art at the time the invention was made that codeine is a functional equivalent of the morphine comprising the combination composition taught and used in the method of constipation taught by Lazarus. For instance, each of the references of Raeder, Mullican, Marketletter, Maurer and Rauk teach administering a combination of oral codeine and acetaminophen to humans in method for the treatment or pain control, but that the administration thereof was accompanied by constipation; and, on page 5, line 3 to page 6, line 12, Lazarus teaches a conversion factor to determine the daily dose of opioids other than morphine or a combination thereof (*e.g.,* hydromorphone, methadone, levorphanol, oxymorphone, meperidine, oxycodone, codeine and pentazocine, *etc.*) to a daily dose of morphine equivalent. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add acetaminophen and to add and/or replace the morphine with codeine taught by the single oral dosage form and method of use thereof taught by the obvious teachings of Lazarus, as set forth immediately above, to provide the instantly claimed inventions because each of Raeder, Mullican, Marketletter, Maurer and Rauk teach that while the oral administration of a combination codeine and acetaminophen to humans provides an effective method of analgesia for the treatment of pain, the administration of the codeine and

acetaminophen bears undesirable side-effects such as constipation; and Lazarus teaches that the simultaneous oral administration of morphine and docusate provides a method for the amelioration of constipation and that other opioid analgesics, such as the instantly claimed codeine, is a functional equivalent of the morphine. Furthermore, with regard to Claim 32 wherein Applicant claims a method wherein the single oral dosage is administered with food, it also would have been obvious to one of ordinary skill in the art, and one would have been motivated and one would have had a reasonable expectation of success to administer the instantly claimed ingredients with food because Maurer teaches a method of providing analgesia comprising the administration of codeine and acetaminophen with food.

Thus, the instantly claimed inventions are no more than the addition of a non-opioid acetaminophen known in the art for its beneficial effect to exert an analgesic effect when orally administered in combination with an analgesic opioid, such as codeine; and, the addition or substitution of one functional equivalent of an opioid analgesic for another, wherein each of morphine and codeine are known in the art to provide an analgesic effect but which are also known to be accompanied with constipation during analgesic use when orally administered to humans. Thus, at the time the invention was made, one of ordinary skill in the art would have been highly motivated and would have had a high expectation of success to add the acetaminophen and to add and/or replace the morphine taught by the single dose form for the prevention of constipation taught by Lazarus to provide the instantly claimed inventions because at the time

the invention was made Lazarus teaches that the simultaneous oral administration an equivalent dose amount of morphine for an opioid analgesic such as codeine in combination with docusate alleviates symptoms of constipation in patients during analgesic use.

Hence, the addition or substitution thereof of the instantly claimed inventions would have been merely a matter of design choice to one of ordinary skill in the art, given that the references before him or her teach the amounts and the beneficial effects and the parameters for the oral administration of the instantly claimed ingredients when administered together to provide an analgesic effect.

According, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 1, 2-5, 10, 11, 21-25, 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al. (N) in view of Kaiko et al. (C).

Applicant's claimed invention of Claims 1, 2, 5, 10, 11, 21 and 25 was set forth above. Applicant further claims the pharmaceutical composition of claim 2, wherein the non-opioid analgesic comprises about 10 mg to about 2000 mg of acetaminophen; and, wherein the non-opioid analgesic comprises about 325 mg to about 750 mg of acetaminophen. Applicant further claims the composition of claim 12, further comprising a non-opioid analgesic in claim-designated amounts.

Applicant further claims the method of claim 21, further comprising a non-opioid analgesic in claim-designated amounts. Applicant further claims the method of claim 21, wherein the single oral dosage form is administered on an empty stomach. Applicant further claims the method of claim 33, wherein the single solid dosage form further comprises a non-opioid analgesic. Applicant further claims the method of claim 34, wherein the non-opioid analgesic comprises about 10 mg to about 2000 mg of acetaminophen; and, wherein the non-opioid analgesic comprises about 325 mg to about 750 mg of acetaminophen. Applicant further claims the method of claim 33, wherein the opioid analgesic is codeine.

The teachings of Brown are set forth above. Brown teaches the claimed inventions except for wherein the instantly claimed pharmaceutical compositions and method of treatment comprise a non-opioid analgesic, namely acetaminophen; and, wherein the pharmaceutical composition is administered on an empty stomach. However, it would have been obvious to one of ordinary skill in the art to add the instantly claimed ingredient to the pharmaceutical composition and to the method of treatment taught by Brown to provide the instantly claimed inventions because at the time the invention was made the addition of acetaminophen to a composition used in the treatment of patients receiving opioid analgesic treatment was known for its beneficial effect, as evidenced by the teachings of Kaiko. For instance, Kaiko teaches a pharmaceutical composition in solid dose form comprising an analgesic opioid, *e.g.*, codeine and hydrocodone, and acetaminophen (non-opioid analgesic) in a

sustained release form for release of the ingredients over a period of time. In Column 11, line 49 to Column 12, line 3, Kaiko teaches that codeine, morphine, meperidine, fentanyl, hydromorphone, oxymorphone, oxycodone, hydrocodone, methadone, propoxphene, pentazocine, levophanol, and combinations thereof may be used in the making of his compositions. In Column 14, lines 27-49, Kaiko teaches that the amount of acetaminophen comprising the reference composition is an amount of about 10 mg to about 2000 mg; and, in an amount of bout 325 mg to about 1000 mg. In Column 34, lines 24-39, Kaiko further teaches orally administering hydrocodone and acetaminophen to patients under fasted conditions. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add the composition comprising acetaminophen taught by Kaiko to the composition used in the method of treatment taught by Brown to provide the instantly claimed inventions because Kaiko teaches that the ingredients comprising the reference composition is analgesically effective when the combination drug is administered orally, but which is aversive in a physically [opioid] dependent subject, in Column 5, lines 14-28. One of ordinary skill in the art would have been further motivated and a reasonable expectation of success to add the acetaminophen and process step of administering the reference composition on an empty stomach taught by Kaiko to the composition and method of treatment taught by Brown to provide the instantly claimed inventions because Kaiko teaches that at the time the invention was made it was known in the art that acetaminophen can act synergistically with opioids and that such

compositions comprising acetaminophen are also said to be subject to less opioid side-effects such as abuse liability, tolerance, constipation and respiratory depression, in Column 14, lines 50-58; and, in Column 34, lines 24-39, Kaiko teaches oral administration of the reference composition to provide the beneficial functional effect of his compositions to human subjects are effective under fasted conditions. Moreover, it is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten,* 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi,* 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett,* 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-77; 126 USPQ 186, 188 (1960). Thus, the instantly claimed inventions are no more than the combining of well-known ingredients and well-known methods for reducing or preventing adverse pharmacological side effects, such as constipation and drug addition, in human subjects receiving analgesic therapy by the oral administration of opioids.

As each of the references indicate that the various proportions and amounts of the ingredients used in the claimed composition or the claimed composition/pharmaceutical combinations, as well, as the method steps for the administration thereof are result variables, they would have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by each of the references.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 1-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al. (N) and Kaiko et al. (C) in view of Colliopoulos (D) and Kais et al. (E).

Applicant's claimed invention of Claims 1, 2-5, 10, 11, 21-25, 30 and 31 was set forth above. Applicant further claims the pharmaceutical composition of claim 1, wherein the stool softener comprises from about 0.1 grams to about 10.0 grams of psyllium; and, wherein the stool softener comprises from about 0.3 grams to about 30.0 grams of psyllium. Applicant further claims the method of claim 21, wherein the stool softener is either psyllium in claim-designated amounts or docusate in claim-designated amounts; and wherein the single oral dosage form is administered with food.

The combined teachings of Brown and Kaiko teach the instantly claimed inventions except for the ingredients, psyllium and docusate; and, the instantly claimed process step for administering the single dosage form with food. However, it would have been obvious to one of ordinary skill in the art to add and/or substitute the stool softener comprising the pharmaceutical composition used in the method of treatment taught by the combined teachings of Brown and Kaiko for the instantly claimed ingredients to provide the instantly claimed pharmaceutical and instantly claimed method of treatment because at the time

the invention was made psyllium and docusate were known in the art for their beneficial functional effect, as evidenced by the teachings of Colliopoulos and Kais. Firstly, Colliopoulos teaches a dietary food composition comprising psyllium having a laxative effective. Secondly, Kais teaches a composition comprising encapsulated dioctyl sulfosuccinate (docusate) and psyllium having a laxative effect. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add and/or substitute the stool softener used in the method of making the pharmaceutical compositions used in the method of treatment taught by the combined teachings of Brown and Kaiko for the instantly claimed ingredients to provide the instantly claimed inventions because Colliopoulos teaches that the reference pharmaceutical compositions comprising psyllium may be dispersed in a palatable food product and orally administered to human subjects to provide a method of treating constipation; and, Kais teaches that that the reference pharmaceutical compositions comprising dioctyl sulfosuccinate (docusate) and psyllium may be used in the making of food products and orally administered to human subjects to provide a method of treating constipation. Moreover, it is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten,* 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi,* 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett,* 47

CCPA 1018, 1020-21; 279 F.2d 274, 276-77; 126 USPQ 186, 188 (1960). Thus, the instantly claimed inventions are no more than the combining of well-known ingredients and well-known methods for reducing or preventing adverse pharmacological side effects, such as constipation and drug addition, in human subjects receiving analgesic therapy by the oral administration of opioids.

As each of the references indicate that the various proportions and amounts of the ingredients used in the claimed composition or the claimed composition/pharmaceutical combinations, as well, as the method steps for the administration thereof are result variables, they would have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by each of the references.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michele C. Flood

MICHELE FLOOD
PATENT EXAMINER

MCF
July 26, 2004